

## APPENDIX II

**Part 1: Editorial amendments to Section 4.8**  
**Risk analysis principles applied by the Codex Committee on Pesticide Residues) of the *Procedural Manual***  
**(For adoption)**

**Note:** Changes are indicated in **bold**, and ~~striketrough~~ or underline.

**4.8 RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES**  
**(As extracted from the 30<sup>th</sup> edition of the Procedural manual of the Codex Alimentarius Commission)**

### Scope

165. This document:

- addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) as the risk management body and **Joint FAO/WHO Meeting on Pesticide Residues** (JMPR) as the risk assessment body; and
- facilitates the uniform application of Section 4.1: Working principles for risk analysis for application in the framework of the Codex Alimentarius.

This document should be read in conjunction with the ~~above mentioned~~ section **mentioned above**.

### General aspects

#### Summary of the maximum residue limit (MRL)-setting process.

166. In addressing pesticide residue issues in Codex, ~~providing advice and taking decisions on risk management is the responsibility of the~~ **Codex Alimentarius** Commission (CAC) and CCPR **are responsible for providing advice and making decisions on risk management**, while **JMPR is responsible for** conducting risk assessments ~~is the responsibility of JMPR~~.

167. The MRL-setting process begins with a Member or Observer nominating a pesticide for evaluation by JMPR. In considering the nomination, CCPR, in consultation with the JMPR ~~Secretariat joint secretaries~~, may ~~then~~ prioritize and schedule the pesticide for evaluation.

168. The WHO Core Assessment Group considers available data encompassing a wide range of toxicological endpoints ~~with the aim of estimating to estimate~~ an **Acceptable Daily Intake (ADI)** and an **Acute Reference Dose (ARfD)** where necessary and if sufficient data are available.

169. The FAO Panel of Experts on Pesticide Residues in Food and the Environment considers data on registered use patterns, ~~residue~~ **fate of residues**, animal and plant metabolism, analytical methodology, and residue data derived from supervised residue trials ~~in order~~ to propose residue definitions and maximum residues levels for ~~the~~ pesticides in food and feed.

170. ~~The~~ JMPR risk assessment includes ~~the estimation of both~~ **estimating** short-term (single-day) and long-term dietary exposures and ~~their comparison~~ **comparing them** with the relevant toxicological benchmarks. MRLs in or on food and animal feeds are based on good agricultural practice (GAP) information, taking into consideration information on dietary intakes, and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.

171. CCPR considers ~~JMPR's the~~ recommendations ~~of JMPR~~ in light of ~~the~~ information provided in the relevant JMPR reports and monographs. MRL recommendations accepted by CCPR are submitted to the Commission for adoption as Codex MRLs (CXLs). An active periodic review programme complements this process.

172. CCPR and JMPR should ensure that their respective contributions to the risk analysis process result in **scientifically based** outputs that are ~~scientifically based~~, fully transparent, thoroughly documented, and available **to Members** in a timely manner ~~to Members~~.

### Risk assessment policy

173. CCPR shall consider the following when preparing its priority list of pesticides for JMPR evaluation:

- a) CCPR's terms of reference;
- b) JMPR's terms of reference;
- c) the Commission's strategic plan; and
- d) nomination requirements and criteria for the prioritization and scheduling of pesticides.

174. When referring pesticides to JMPR, CCPR shall provide background information and clearly specify the reasons for the request when pesticides are nominated for evaluation.

175. When referring to pesticides to JMPR, CCPR may also refer **to** a range of risk management options, with a view to obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option. CCPR shall request JMPR to review any risk assessment policies, methods, and guidelines being considered by CCPR for assessing MRLs **for** pesticides.

176. When establishing its standards, CCPR shall clearly state when it applies any considerations based on other legitimate factors<sup>1</sup> relevant for the health protection of consumers and **for** the promotion of fair practices in food trade, in addition to JMPR's risk assessment and recommended MRLs, and specify its reasons for doing so.

177. JMPR applies a transparent, science-based risk assessment process for establishing an ADI and ARfD, where appropriate.

178. JMPR, in consultation with CCPR, must continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments.

179. The JMPR Secretariat shall consider whether these minimum data requirements have been met when preparing the provisional agenda for **JMPR** meetings **of JMPR**.

### **MRLs for specific groups**

#### **MRLs for foods of animal origin**

180. Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed (e.g. forage crops, plant parts that could be used in animal feeds, by-products, or co-products of industrial productions). The results of farm animal feeding studies and residues in animal feed **also** serve **also** as a primary source of information for estimating maximum residue levels in foods of animal origin.

181. If no adequate studies are available, no MRLs will be established for foods of animal origin. MRLs for feeds **s** (and the primary crops) should not be established in the absence of animal transfer data. Where **the exposure of** livestock **exposure** to pesticides through feeds **s** leads to residues at the **limit of quantification (LOQ)**, MRLs at the LOQ must be established for foods of animal origin. MRLs should be established for groups of foods of animal origin, for example, edible offal (mammalian), if animals are exposed to pesticide residues via animal feed, and for specific foods, for example, cattle kidney, in cases where animals are directly treated with a pesticide.

182. If the recommended MRLs or limits for foods of animal origin resulting from direct treatment of the animal and residues from animal feed do not agree, the higher recommendation will prevail regardless of whether they are recommended by JMPR or **the Joint Expert Committee on Food Additives (JECFA)**.

#### **MRL for fat-soluble pesticides**

183. If a pesticide is determined as "fat soluble" after consideration of the following factors, it is indicated with the text "the residues are fat soluble" in the residue definition:

- a) When available, information concerning the partitioning of the residue (as defined) in muscle versus fat or residue in whole milk versus milk fat in the metabolism studies and livestock feeding studies determines the designation of a residue as being "fat soluble".
- b) In the absence of useful information on the distribution of residues in muscle and fat or in milk or milk fat, residues with octanol-water partition coefficient (log Pow) > 3 are likely to be "fat soluble".

184. For milk and milk products, two maximum residue levels would be estimated for fat-soluble pesticides, if the data permits: one MRL for whole milk and one for milk fat. When needed, MRLs for milk products can then be calculated from the two values, by taking into account the fat content and the contribution from the non-fat fraction.

185. For **the** regulation and monitoring of residues of fat-soluble pesticides in milk, where CXLs have been established for both whole milk and milk fat, whole milk should be analysed, and the result should be compared with the CXLs for whole milk.

<sup>1</sup> Statement of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account (Appendix section A1.1).

### MRLs for spices

186. MRLs for spices can be established ~~on the basis of~~ **based on** monitoring data in accordance with the guidelines established by JMPR.

### MRLs for processed or ready-to-eat foods or feeds

187. JMPR evaluates processing studies to derive processing factors used to estimate residue concentrations in processed foods or feeds for dietary risk assessments and, if necessary, recommends MRLs for processed foods or feeds.

188. CCPR:

- a) establishes MRLs for important processed foods and feeds moving in international trade;
- b) establishes MRLs for processed foods and feeds only if the resulting value is higher than the MRL established for the corresponding raw agriculture commodity (RAC), processing factor > 1.3 (PF > 1.3);
- c) continues the practice of establishing MRLs for processed foods and feeds where, due to the nature of the residues during some specific process, significant amounts of relevant metabolites appear or increase; and
- d) supports the current JMPR practice of evaluating all processing studies provided and including in each evaluation or review a summary table of all validated processing factors.

### MRLs for minor crops

189. Guidance **by CCPR** to facilitate the establishment of MRLs for pesticides for minor crops ~~by CCPR~~ is provided in Annex D.

### Establishment of extraneous maximum residue limits (EMRLs)

190. The EMRL refers to a pesticide residue or a contaminant arising from environmental sources due to former agricultural uses, not from the use of the pesticide directly or indirectly on the food or feed. It is the maximum concentration of a pesticide residue that is recommended by the Commission to be legally permitted or recognized as acceptable in or on a food or animal feed.

191. Pesticides for which EMRLs are most likely ~~to be~~ needed are persistent in the environment for a relatively long period after uses has been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

192. All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade. JMPR has developed a standard format for reporting pesticide residues monitoring data.

193. JMPR compares data distributions in terms of the likely percentages of violations that might occur if a given EMRL is proposed to CCPR.

194. Because residues gradually decrease, CCPR evaluates **the existing EMRL, if possible,** every five years, ~~if possible,~~ **the existing EMRL,** based on the reassessments of JMPR.

### Risk assessment

#### Role of JMPR

195. JMPR consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Directors-General of FAO and WHO, according to the rules of both organizations. **It is,** charged with **the task of** providing scientific advice on pesticide residues.

196. JMPR is primarily responsible for performing the risk assessments and proposing MRLs upon which CCPR and ultimately the Commission base their risk management decisions. JMPR proposes MRLs based on residue data from GAP/registered uses or, in specific cases, such as EMRL and MRL for spices, based on monitoring data.

197. JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by the Commission, namely hazard identification, hazard characterization, exposure assessment, and risk characterization, that can serve as the basis for CCPR's discussions.

198. JMPR should identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment **in regard to regarding** the general population and to particular subpopulations, and shall, as far as possible, identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

199. JMPR communicates to CCPR possible sources of uncertainties in the exposure assessment and/or in the ~~pesticide's~~ hazard characterization ~~of the pesticide~~ that, if resolved, would allow a refinement of the risk assessment.

### Dietary intake

200. JMPR is responsible for evaluating exposure to pesticides. JMPR must strive to base its exposure assessment and, hence, the dietary risk assessments on global data, including that from developing countries. In addition to ~~the~~ global environment monitoring system ~~(GEMS) (GEMS)~~ Food data, consumption monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are based on the available high percentile consumption data provided by Members and compiled by GEMS/Food.

201. ~~In undertaking dietary exposure risk assessments to assist CCPR,~~ JMPR uses the WHO and FAO guidance documents ~~to undertake dietary exposure risk assessments to assist CCPR.~~<sup>ii, iii</sup> ~~For dietary intake purposes,~~ JMPR recommends supervised trial median residues (STMRs) and highest residues (HRs) ~~for dietary intake purposes.~~

202. JMPR establishes the ADI and calculates the international estimated daily intake (IEDI). JMPR also establishes ARfDs, where appropriate, and indicates cases where an ARfD is ~~not necessary unnecessary~~. Where an ARfD is set, JMPR calculates the international estimate of short-term intake (IESTI) for the general population and ~~for~~ children (under six years old), following a procedure described by JMPR.

203. JMPR uses the most up-to-date and most refined residue and consumption data available to calculate the IEDI. When the IEDI exceeds the ADI in one or more of the GEMS/Food cluster diets, JMPR flags this situation when recommending maximum residue levels to CCPR. JMPR also indicates relevant data to refine the IEDI.

204. Where the IESTI exceeds the ARfD for a pesticide/food combination, the JMPR report should describe the particular situation that gives rise to that acute intake concern. JMPR shall indicate the ~~possibilities to refine possibility of refining~~ the IESTI.

205. If either IESTI exceeds the ARfD or IEDI exceeds ADI, JMPR indicates that ~~the provision of~~ additional data would be necessary to refine these calculations. Members/Observers have the opportunity to supply the new data and shall commit to ~~provide them providing it~~ in accordance with the four-year rule.

206. In these cases, the four-year rule is applied when insufficient data have been submitted to set a new CXL. Members/Observers may ~~provide a~~ commitment to JMPR and CCPR to provide the necessary data for evaluation within four years. The proposed MRL is maintained for a period of no more than four years, pending the evaluation of the additional data. A second period of four years is not granted. If there is no commitment to provide additional information, or no data are supplied despite a commitment being made in relation to the four-year rule, CCPR considers withdrawal of the draft MRL.

207. ~~The estimate of the Estimating~~ short-term dietary intake requires substantial food consumption data ~~that are, which are~~ currently ~~are~~ only sparsely available. Governments are urged to generate relevant consumption data and ~~to~~ submit ~~these data it~~ to ~~the~~ WHO.

### Risk management

#### Role of CCPR

208. CCPR is primarily responsible for recommending risk management proposals, such as MRLs, for adoption by the Commission.

209. CCPR shall base its risk management recommendations to the Commission on JMPR's risk assessments of the respective pesticides, considering, where appropriate, other legitimate factors<sup>ii</sup> relevant ~~for to consumer~~ health protection ~~of consumers~~ and ~~for~~ the promotion of fair practices in food trade.

210. In cases where JMPR has performed a risk assessment and CCPR or the Commission determines that additional scientific guidance is necessary, CCPR or the Commission may ~~make a specific specifically~~ request ~~to that~~ JMPR ~~to~~ provide further scientific guidance necessary for a risk management decision.

211. CCPR's risk management recommendations to the Commission shall take into account the relevant uncertainties as described by JMPR.

212. CCPR shall consider only MRLs recommended by JMPR.

213. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns. ~~The GEMS/Food diets are used to and~~ assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but ~~on~~ available consumption data provided by Members and compiled by GEMS/Food.

214. If no validated methods of analysis are available for enforcing an MRL for a specific pesticide, ~~no MRL will be established by~~ CCPR ~~will not establish one~~.

#### Selection of pesticides for JMPR evaluation

215. Each year, CCPR, in cooperation with the JMPR Secretariat, agrees on a schedule of JMPR evaluations in the following year and considers prioritization of other pesticides for future scheduling.

#### Procedure for the preparation of the schedules and priority lists

216. CCPR submits the schedules and priority lists of pesticides for JMPR evaluation to the Commission for approval each year, as new work, and requests the re-establishment of the **Electronic Working Group (EWG)** on priorities.

217. The EWG on priorities is tasked with preparing a schedule of pesticides for JMPR (evaluations for the following year) for ~~the~~ consideration ~~of by~~ CCPR and ~~the maintenance of~~ **maintaining** a priority list of pesticides for future scheduling by CCPR.

218. The schedules and priority lists are provided in the following tables:

- a) Table 1 – CCPR proposed schedule and priority lists of pesticides (new pesticides, new uses, and other evaluations).
- b) Table 2A – Schedule and priority lists of periodic reviews.
- c) Table 2B – Periodic review list (pesticides that ~~have been~~ **were** last evaluated 15 years ago or more, but not yet scheduled or listed, 15-year rule).
- d) Table 3 – Record of periodic review.
- e) Table 4 – Pesticide/Food combinations for which specific GAP is no longer supported.

219. Each year, the Codex Secretariat issues an **invitation** letter, one month after the Commission, seeking applications for membership of the EWG on priorities.

~~220. In early September of each year. At least six months prior to the next session of CCPR,~~ the EWG Chair will issue a ~~message broadcast email~~ to Members/Observers of the EWG requesting nominations for:

- a) new pesticides;
- b) new uses of pesticides previously reviewed by JMPR;
- c) other evaluations to address, for example, review of toxicological endpoint and alternative GAP; and
- d) periodic reviews of pesticides for which there are concerns, including public health.

221. Nominations for new pesticides and new uses of pesticides previously reviewed by JMPR are submitted by Members/Observers to the EWG Chair and the JMPR ~~Joint~~ Secretariat using the form in the FAO Manual.<sup>iv</sup>

222. The nomination form shall provide a clear indication of the availability of data and national evaluations, as well as give an indication of the number of crops and residue trials to be evaluated. The request should also indicate the current status of national registrations for the pesticide.

223. Nominations for other evaluations and periodic reviews should be submitted, on the concern forms, Annex A and Annex B, respectively, with accompanying scientific data addressing the relevant concern. ~~For periodic reviews, the~~ **The** request should also provide information on the most recent evaluation, ADI, and ARfD **for periodic reviews**.

224. Nominations complying with the requirements are incorporated into a list, prioritized, and scheduled according to the criteria specified below:

- a) Those received **at least two months of the request for nominations by 30 November** are incorporated into the draft agenda paper, which is distributed as a circular letter **at least four months prior to the next session of CCPR in early January**.
- b) Members and Observers are allowed two months from the **date of** distribution **date** to provide comments to the EWG Chair and JMPR ~~Joint~~ Secretariat.
- c) ~~On the basis of~~ **Based on** comments received in response to the circular letter, the EWG Chair incorporates the new nominations into the schedule and priority lists and prepares an agenda paper for CCPR. The schedule seeks to ~~provide a~~ balance **of** new pesticides, new uses, other evaluations, and periodic reviews.
- d) Following plenary discussions on MRL recommendations, the EWG Chair revises the schedule and priority list, which is ~~then~~ presented as a conference room document (CRD) for CCPR's consideration. To cover the

possibility that a Member  ~~/~~ or Observer cannot meet the JMPR data call-in deadline for new pesticide evaluations, CCPR will include reserve pesticides.

- e) Following plenary discussion on CRD, CCPR will agree on a JMPR evaluation schedule for the following year. The final schedule will take into account available JMPR resources.
- f) At this point, the schedule will be closed for the inclusion of additional pesticides. However, with the agreement of the JMPR Secretariat, the inclusion of additional foods or feeds for scheduled pesticides may be accepted.

#### **Nomination requirements and criteria for the prioritization and scheduling of pesticides for evaluation by JMPR**

##### **New pesticides**

##### ***Nomination requirements***

225. Before a nomination is accepted, the following requirements must be met:

- a) an intention to register the pesticide for use in a Member Nation;
- b) the foods or feeds proposed for consideration should be traded internationally;
- c) there is a commitment by the Member/Observer of the pesticide to provide supporting data for review in response to the JMPR "data call-in";
- d) the use of the pesticide is expected to give rise to residues in or on a food or feed moving in international trade;
- e) the pesticide has not ~~been~~ already ~~been~~ accepted for consideration; and
- f) the nomination form has been completed.

##### ***Prioritization criteria***

226. The following criteria are applied when preparing the schedules and priority lists:

- a) the period of time since the pesticide was nominated for evaluation; a pesticide that was nominated first will have higher priority;
- b) timing of data availability;
- c) commitment by the Member/Observer to provide supporting data for review with a firm date for data submission; and
- d) the provision of information on the foods or feeds for which CXL are sought and the number of trials for each food or feed.

##### ***Scheduling criteria***

227. ~~In order for~~ For CCPR to schedule a pesticide for JMPR evaluation in the following year:

- a) it must be registered for use in a Member Nation and formulation labels made available by the time of ~~the~~ JMPR "data call-in"; and
- b) if the use of the pesticide does not give rise to detectable residues in foods and feeds, it will be afforded a lower priority than those listed pesticides for which use does give rise to measurable residues.

##### **New uses of pesticides previously reviewed by JMPR**

##### ***Nomination requirement***

228. At the request of a Member/Observer, pesticides previously evaluated by JMPR may be listed in Table 1 for the inclusion of additional uses.

##### ***Prioritization criteria***

229. When prioritizing new use evaluations, the EWG on priorities will consider the following criteria:

- a) the date the request was received; ~~and~~
- b) commitment by the Member/Observer to provide the required data for review in response to the JMPR "data call-in".

##### ***Scheduling criteria***

230. Scheduling criteria are specified in the new pesticide section (paragraph 227).



## Other evaluations

### *Nomination requirements*

231. Pesticides previously evaluated by JMPR may be listed for further toxicological and/or residue evaluations by JMPR as a result of requests from CCPR or Members when:

- a) a Member seeks to obtain a revised MRL for one or more foods or feeds; for example, **based on the basis of** alternative GAP;
- b) CCPR requests a clarification or reconsideration of a recommendation from JMPR;
- c) new toxicological data becomes available to indicate a significant change in **the the** ADI or ARfD;
- d) a data deficiency is noted by JMPR during a new pesticide evaluation or periodic review and Members/Observers will supply the required information; and
- e) CCPR elects to schedule the pesticide under the four-year rule.

232. In this case, the four-year rule is applied when insufficient data have been submitted to confirm or amend an existing CXL. The CXL is recommended for withdrawal. However, Members/Observers may provide a commitment to JMPR and CCPR to provide the necessary data for review within four years. The existing CXL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

### *Prioritization criteria*

233. When prioritizing pesticides for other evaluations, the EWG on priorities will consider the following criteria:

- a) the date the request was received;
- b) commitment by the Member/Observer to provide the required toxicological and/or residue data for review in response to the JMPR "data call-in";
- c) whether the data is submitted under the four-year rule for evaluations; and
- d) the reason for its submission; for example, a request from CCPR.

### *Scheduling criteria*

234. Scheduling criteria are as specified in the new pesticides section.

### *Periodic review*

235. Pesticides that have not been reviewed toxicologically for more than 15 years and/or not had a significant review of CXL for 15 years will be listed in Table 2B of the schedules and priority lists.

236. Pesticides listed in Table 2B should be considered for scheduling for periodic review when concerns, including public health concerns, are identified and nominated for inclusion in Table 2A. The nominating Member should submit the concern form in Annex B and accompanying relevant scientific information substantiating the concern for consideration by the JMPR Secretariat/EWG on priorities.

237. Pesticides listed in Table 2B may be nominated for inclusion in Table 2A and thus considered for scheduling for periodic review **on the basis of based on** the availability of data necessary for the review. The nominating Member should submit an inventory and brief explanation of the relevant toxicological and residue data package for consideration by the JMPR Secretariat/EWG on priorities. The Member should inform the EWG on priorities, whether all or some CXLs will be supported, and **should** specify each supported and unsupported CXL.

238. Pesticides listed in Table 2B, for which no periodic review has been undertaken for 25 years, will be brought to the attention of CCPR **with a view** to transfer to Table 2A and subsequent scheduling.

239. Pesticides which have been the subject of a periodic review during the previous 15 years, and thus are not listed in Table 2B, may be considered for transferring to Table 2A, where a concern form in Annex B and accompanying scientific information, upon review, demonstrates a public health concern.

### *Scheduling and prioritization criteria for pesticides listed in Table 2A*

240. The EWG on priorities and CCPR will consider the following periodic review criteria:

- a) if scientific data concerning the intake and/or toxicity profile of a pesticide indicates some level of public health concern;
- b) if no ARfD has been established by Codex or if an established ADI or ARfD are of public health concern and

information is available from Members on national registrations and/or the conclusions from national/regional evaluations indicated a public health concern;

- c) the availability of current labels (authorized GAP) arising from recent national reviews;
- d) CCPR has been advised by a Member that the residues from a pesticide has been responsible for trade disruption;
- e) the date the data will be submitted;
- f) if there is a closely related pesticide that is a candidate for periodic review that can be evaluated concurrently; and
- g) CCPR agrees to schedule the pesticide under the four-year rule.

241. In this case, the four-year rule is applied when insufficient data have been submitted to confirm or amend an existing CXL. The CXL is recommended for withdrawal. However, Members/Observers may provide a commitment to JMPR and CCPR to provide the necessary data for review within four years. The existing CXL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

### **Periodic review procedure**

#### ***Identify pesticides for periodic review and solicit data commitments***

242. Pesticides are listed for periodic review according to the process and procedures described in Section 4.8: Risk analysis principles applied by the Codex Committee on Pesticide Residue (paragraph 215). The process provides Members/Observers a notice of a periodic review.

243. When a pesticide is listed for periodic review, Members/Observers are able to support it, regarding the two following possibilities:

- a) Case A: The pesticide is supported by the original sponsor, who is committed to submit a complete data package to meet JMPR's data requirements.

If the original sponsor does not support some uses, Members/Observers may support them.

- b) Case B: The pesticide is not supported by the original sponsor; in this case, interested Members/Observers may support the review of the pesticide.

#### ***Commitment to support pesticides or existing CXL or new proposed MRL***

244. The commitment of Members/Observers to provide data for the periodic review should be addressed to the Chair of the EWG on priorities and the JMPR ~~Joint~~ Secretariat according to the FAO Manual<sup>23</sup> and the considerations of JMPR on pesticides no longer supported by the original sponsor.

245. For Case A and Case B, data should be submitted in accordance with the guidance of JMPR for the respective cases:<sup>i</sup>

- a) in cases where some uses are not supported by the manufacturer but are supported by Members/Observers;
- b) if the current GAP support the current CXL, justification for it as well as relevant labels are required; and
- c) if GAP were modified, supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRL in animal and processed foods are required.

### **ELABORATION PROCEDURE**

#### **Utilization of the an accelerated procedure approach for the elaboration of MRLs (Step 5/8 procedure)**

246. In order to accelerate the adoption of a proposed MRL, CCPR can recommend to the Commission to omit Steps 6 and 7 and adopt the proposed MRL at Step 8. This procedure is called approach is referred to as "adoption at Step 5/8 procedure". The preconditions for the utilization of adoption at Step 5/8 procedure are:

- a) the new proposed MRL is circulated at Step 3;
- b) the JMPR report is available electronically by early February, at least four months prior to the next session of CCPR; and
- c) no intake concerns were identified by JMPR.



247. If a delegation has a concern with advancing a given MRL, a concern form in Annex A must be submitted following the procedure described in the Procedure for submitting concerns and clarifications, later in this section, at least one month before the CCPR session.

248. If that concern is addressed at the CCPR session and the JMPR position remains unchanged, CCPR will decide if the MRL will be advanced to Step 5/8 ~~procedure~~.

249. If the concern cannot be addressed at the CCPR session, the MRL will be advanced to Step 5 at the CCPR session, and the concern will be addressed by JMPR according to the procedure described in paragraphs 255–260: Procedure for submitting concerns and clarifications. Any other draft MRLs for the pesticide, satisfying the above conditions, should be advanced to Step 5/8 ~~procedure~~.

250. The result of the consideration of the concern by JMPR will be considered at the next CCPR session. If the JMPR position remains unchanged, CCPR will decide if the MRL will be advanced to Step 8.

251. If either IEDI exceeds ADI or IESTI exceeds ARfD in one or more cluster diets, or the ARfD is exceeded in one or more foods or feeds, the accelerated ~~procedure~~ **approach** shall not be applied, and the procedure described in paragraphs 200–207: Dietary intake applies.

#### REVOCATION OF CXLs

252. CXLs are proposed for revocation in the following scenarios:

- a) as a result of the periodic review procedure including CXLs of pesticides that have not been reviewed for more than 25 years and are not supported by any Member/Observer;
- b) where new scientific data, following the JMPR risk assessment, indicate that the pesticide use may compromise human health;
- c) the pesticide is no longer produced and commercialized, and there is no remaining stock;
- d) the pesticide is produced but is not used in food or feed; and
- e) there is no international trade of foods or feeds in which the pesticide may have been used.

253. When a pesticide meets one or more of conditions (a–e), its CXL list will be included in the agenda for the next CCPR session for the committee to consider a recommendation to the Commission for revocation of the CXL. Decisions of the Commission on revocation of CXL will take effect a year after the close of the session of the Commission where such decisions were made.

254. If a pesticide meeting the above stated conditions is environmentally persistent, the need for EMRLs to cover international trade should be considered before its CXLs are revoked. A Member/Observer should indicate the need to maintain CXLs for a period not exceeding four years. Within that period, Members/Observers will be requested to provide monitoring data to allow EMRLs to be established. CCPR will make a decision to establish EMLs when JMPR has evaluated monitoring data and all CXLs will be revoked.

#### PROCEDURE FOR SUBMITTING CONCERNS AND CLARIFICATIONS

##### Concerns with the advancement of an MRL or the evaluation of a pesticide

255. If Members intend to express concerns with advancement of an MRL or the evaluation of a pesticide, they should complete and submit the concern form in Annex A to the Codex and ~~the~~ JMPR ~~Secretariat Secretaries~~ accompanied by scientific data at least one month before the CCPR session.

256. JMPR will evaluate the scientific data provided with the concern form. CCPR will decide whether JMPR should address the concern and schedule it based on JMPR recommendations and workload.

257. When a concern form is not submitted one month prior to the CCPR session, JMPR will consider the concern at a following meeting and CCPR would subsequently decide on the status of the MRL.

258. When considering concerns expressed by Members, CCPR should recognize the position taken by JMPR as the best available scientific opinion (applicable at the international level) until and if a different position is indicated.

259. Science-based concerns based on the same data/information should be considered only once by JMPR in relationship to any specific pesticide, MRL or CXL.

260. If the same information is submitted, JMPR should simply note that this information has already been reviewed and therefore no further review is warranted.

### Concerns with public health on previously evaluated pesticides

261. If Members intend to express a public health concern on a previously evaluated pesticide for prioritization, they should complete and submit the form in Annex B along with the accompanying relevant scientific information substantiating the concern to the Chair of EWG on priorities and the JMPR **Secretariat Secretaries**, in accordance with paragraph 215: Selection of pesticides for JMPR evaluation based on their potential higher concern regarding public health.

262. JMPR, in consultation with the EWG on priorities, will consider whether the submitted information indicates some level of public health concern and present proposals at the subsequent CCPR session.

263. If the concern in regard to a pesticide is supported by CCPR, the pesticide will be assigned a high priority and scheduled for the next available year.

264. However, if a Member or Observer disagrees with the proposal by the EWG on priorities, it must lodge additional scientific data to the Chair of the EWG on priorities one month before the next CCPR session. At the following CCPR session, the EWG on priorities will report its proposal. CCPR will make its final decision on prioritization.

### Request for clarification

265. If Members seek clarification on a pesticide, they must complete the form provided in Annex A and indicate the specific parts of the JMPR evaluation for which they seek clarification. Such requests must be included in the response to relevant Codex circular letters or other Codex papers. JMPR will address such requests for clarification during the next JMPR meeting and provide a response to such requests by the following CCPR session. CCPR will record any responses or changes in decisions made resulting from the request for clarification. Pending JMPR's respond to the request of the clarification, the MRL relevant to the request can proceed through the Codex 5/8 Step process for the elaboration of CXL.

### Addressing differences in procedures for risk assessment

266. MRLs should not be prevented from advancement when there is a science-based concern regarding current JMPR risk assessment procedures that JMPR has addressed through the concern form process. However, where differences exist in procedures for risk assessment (i.e. use of variability factor, use of human studies) it is imperative that CCPR/JMPR attempt to address these differences in order to limit them where possible. Appropriate action by CCPR to address these issues may include referring the issue:

- a) to JMPR if there is additional or new information, or if CCPR wishes to provide risk management input to JMPR on the conduct of risk assessments;
- b) to national governments or regional authorities for input with a discussion and decision at the next CCPR; and/or
- c) where justified by its nature, to a scientific consultation if the resources are available. Members recommending any such action by CCPR should provide information supporting their recommendation for the consideration of the committee.

### RISK COMMUNICATION

267. In accordance with Section 4.1: [Working principles for risk analysis for application in the framework of the Codex Alimentarius](#), CCPR, in cooperation with JMPR, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner to Members and Observers.

268. In order to ensure the transparency of the assessment process in JMPR, CCPR provides comments on the guidelines related to assessment procedures being drafted and published by JMPR.

269. CCPR and JMPR recognize that good communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.

270. CCPR and JMPR must continue to develop procedures to enhance communication between the two bodies.

<sup>i</sup> FAO. 2009. *Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed*. FAO Plant Production and Protection Paper, 197. Rome.

<sup>ii</sup> WHO.1997. *Guideline for predicting dietary intake of pesticide residues*. Joint UNEP/FAO/WHO Food Contamination Monitoring Programme in collaboration with the Codex Committee on Pesticide Residues. Geneva.

<sup>iii</sup> FAO. 2003. *Pesticide Residues in Food 2003 Report*. FAO Plant Production and Protection Paper No.176, Rome. Chapter 3.

<sup>iv</sup> FAO and WHO. 2016. *Manual on the development and use of FAO and WHO specifications for pesticides*. FAO Plant Production and Protection Paper, No. 228. Rome, FAO

**Part 2: Correction to the definition of “fat” in the *Classification of food and feed* (CXA 4-1989)****(For adoption)****Note:** Changes are indicated in **bold**, and ~~striketrough~~ or underline.**Mammalian fats (except fat from marine mammals)****Class B****Type 06****Mammalian products****Group 031****Group Letter Code MF**

Group 031. Mammalian fats, excluding milk fats are derived from the fatty tissues of animals (not processed). For processed animal fats see Group 085.

Exposure to pesticides is through animal metabolism following oral intake with feed or through dermal intake as a consequence of external use of the pesticides against ectoparasites.

The entire commodity may be consumed.

Fat is the ~~food-lipid~~-based tissue that is trimmable from an animal carcass or cuts from an animal carcass. It may include **subcutaneous**, omental, or perirenal fat. It does not include interstitial or intramuscular carcass fat or milk fat.

Portion of the commodity to which the MRL applies (and which is analysed): **Whole commodity.**

The scientific species names of the relevant animals are not repeated for this group of commodities. For these names see Group 030 Muscle (from mammals other than marine mammals).